

- 1 1. A capsule for sustained release of a combination of acetaminophen of from 100 mg to
2 1,000 mg and tramadol or its salts of from 15 mg to 150 mg comprising:
3
- 4 1) An immediate release portion comprising 25% - 75% of the total effective amount
5 of drugs in the form selected from pellets, beads, granules and mini-tablets.
6 2) A sustained release portion comprising:
7 a. 25% - 75% of the total effective amount of drugs in the form selected from
8 pellets, beads, granules and mini-tablets;
9 b. 6% - 50% of gelling polymers of the total formulation, and said the
10 sustained release portion may or may not comprise an enteric coating at a
11 level of 5% - 40% of the total formulation.
12
- 13 2. A capsule, as set forth in Claim 1, releases 25% - 60% of the total drug in the first hour
14 in a simulated gastric fluid dissolution media, 50% - 90% of the total drug in the first four
15 hours and not less than 80% of the total drug in the first 12 hours in a simulated intestinal
16 fluid dissolution media using USP dissolution method II at 50 rpm.
17
- 18 3. A capsule, as set forth in Claim 1, comprises at least one gelling polymer selected
19 from hydroxy propyl methylcellulose, hydroxypropyl ethylcellulose, hydroxypropyl
20 cellulose, hydroxy ethylcellulose, methylcellulose, xanthan gums, alginate salts,
21 polyethylene oxide, carboxyvinyl polymer, or a salt of a carboxymethyl cellulose, said
22 gelling polymer having a viscosity within the range of from about 60 to about 7,000,000
23 centipoises, and preferably from about 100 to about 100,000 centipoises, in a 2% by
24 weight water solution at 25°C, as measured by a Brookfield LV viscometer.
25
- 26 4. The pellets, beads, granules and mini-tablets in the capsule, as set forth in Claim 1,
27 may or may not be coated with enteric polymers selected from polyacrylate material,
28 cellulose acetate phthalate, cellulose phthalate hydroxy propyl methyl ether, polyvinyl
29 acetate phthalate, hydroxy propyl methyl cellulose acetate succinate, cellulose acetate
30 trimellitate, or a shellac.

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2 5. A tablet for sustained release of a combination of acetaminophen of from 100 mg to
3 1,000 mg and tramadol or its salt of from 15 mg to 150 mg comprising:
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5 1) A sustained release portion comprising:

6 a. 25% - 75% of the total effective amount of drugs;

7 b. 6% - 50% of gelling polymers of the total formulation, and said the
8 sustained release portion may or may not comprise an enteric coating at a
9 level of 5% - 40% of the total formulation;

10 2) An immediate release portion comprising 25% - 75% of the total effective amount
11 of drugs, layered or compressed on the sustained release portion.
12

13 6. A tablet, as set forth in Claim 5, releases 25% - 60% of the total drug in the first hour
14 in a simulated gastric fluid dissolution media, 50% - 90% of the total drug in the first four
15 hours and not less than 80% of the total drug in the first 12 hours in a simulated intestinal
16 fluid dissolution media using USP dissolution method II at 50 rpm.
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18 7. A tablet, as set forth in Claim 5, comprises at least one gelling polymer selected from
19 hydroxy propyl methylcellulose, hydroxypropyl ethylcellulose, hydroxypropyl cellulose,
20 hydroxy ethylcellulose, methylcellulose, xantham gums, alginate salts, polyethylene
21 oxide, carboxyvinyl polymer, or a salt of a carboxymethyl cellulose, said gelling polymer
22 having a viscosity within the range of from about 60 to about 7,000,000 centipoises, and
23 preferably from about 100 to about 100,000 centipoises, in a 2% by weight water solution
24 at 25°C, as measured by a Brookfield LV viscometer.
25

26 8. The sustained release portion, as set forth in Claim 5, may or may not be coated with
27 enteric polymers selected from polyacrylate material, cellulose acetate phthalate,
28 cellulose phthalate hydroxy propyl methyl ether, polyvinyl acetate phthalate, hydroxy
29 propyl methyl cellulose acetate succinate, cellulose acetate trimellitate, or a shellac.
30

1 9. A sustained release dosage form comprising:

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3 1) A sustained release portion comprising:

4 a. 25% - 75% of the total effective amount of drugs;

5 b. 6% - 50% of gelling polymers of the total formulation, and said the
6 sustained release portion may or may not comprise an enteric coating at a
7 level of 5% - 40% of the total formulation;

8 2) An immediate release portion comprising 25% - 75% of the total effective
9 amount of drugs, layered or compressed on the sustained release portion.

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11 10. A sustained release dosage form, as set forth in Claim 9, releases 25% - 60% of the
12 total drug in the first hour in a simulated gastric fluid dissolution media, 50% - 90% of
13 the total drug in the first four hours and not less than 80% of the total drug in the first 12
14 hours in a simulated intestinal fluid dissolution media using USP dissolution method II at
15 50 rpm.

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17 11. A sustained release dosage form, as set forth in Claim 9, comprises at least one
18 gelling polymer selected from hydroxy propyl methylcellulose, hydroxypropyl
19 ethylcellulose, hydroxypropyl cellulose, hydroxy ethylcellulose, methylcellulose,
20 xantham gums, alginate salts, polyethylene oxide, carboxyvinyl polymer, or a salt of a
21 carboxymethyl cellulose, said gelling polymer having a viscosity within the range of
22 from about 60 to about 7,000,000 centipoises, and preferably from about 100 to about
23 100,000 centipoises, in a 2% by weight water solution at 25°C, as measured by a
24 Brookfield LV viscometer.

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26 12. The sustained release portion, as set forth in Claim 9, may or may not be coated with
27 enteric polymers selected from polyacrylate material, cellulose acetate phthalate,
28 cellulose phthalate hydroxy propyl methyl ether, polyvinyl acetate phthalate, hydroxy
29 propyl methyl cellulose acetate succinate, cellulose acetate trimellitate, or a shellac.